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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/020,716	02/09/1998	RUDOLF JUNG	0815	3572
27310	7590	11/18/2003		
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131				
			EXAMINER MCEI.WAIN, ELIZABETH F	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/020,716

Applicant(s)

JUNG ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendments filed June 30, 2003 and July 16, 2003 have been entered.

Claims 78, 79, 90, 91, 96, 103, 105 and 108 are newly amended.

Claims 1-77, 80-89, 92-95, 97-102, 104, 106, 107 and 109-111 have been cancelled.

Claims 112-120 are newly added.

Claims 114-116 are once amended.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 are pending and are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections that are not restated below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 112-120, and all claims dependent thereon, are indefinite in the recitation of “native plant seed protein”, since it is unclear what the metes and bounds of this term would be. Is this term intended to mean any protein that is or can be produced in a plant seed, or proteins that are only produced in plant seeds, for example? The specification fails to further define or clarify the use of this term. Furthermore, the use of “native” is confusing as it pertains to a modified protein, since a modified protein is not a native protein.

Claims 113-120, and all claims dependent thereon, are indefinite in that they are unduly alternative in the multiple recitations of “and/or” in the claims.

Claims 114-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to recite “chimeric”. However, it appears that there is no support for this term in the specification. While, applicant has pointed to page 5, lines 16-17, the term “chimeric” is not found.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification teaches a transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed cereal plant seed) comprising the modified hordothionin gene of SEQ ID NO: 2 (HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene.

The specification does not teach the range of 7 mole% to 40 mole % of lysine or 6 mole% to 40 mole % of sulfur-containing amino acids for any seed protein and further does not

teach any seed proteins having both of these ranges. Therefore, in view of the reasons of record set forth in the scope of enablement rejection set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001; and given the lack of working examples of protein coding sequences having the claimed ranges of mole % lysine and sulfur containing amino acids; the absence of guidance with regard to identifying such sequences and transforming them into plants; and given the breadth of the claims which encompass seed proteins that have virtually unlimited modifications to produce proteins having the claimed ranges of mole % lysine and sulfur containing amino acids; it would require undue experimentation by one of ordinary skill in the art to make and/or use the claimed invention.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn given that the specification demonstrates increased lysine obtained by using one construct of HT12 and an endosperm specific promoter, and the Declaration of Jung provides results on using a construct comprising ESA and an endosperm specific promoter. The Examiner maintains that the rejection is proper given that applicants one working example is not sufficient to enable the broad claims. As stated in the last office action, the example provided in the Declaration of Jung does not provide information to support the claims.

Applicants assert that the specification and prior art provide many suitable nucleotides for increasing lysine and sulfur containing amino acids, and state that "the Examiner has not provided any evidence that the information disclosed in the application does not lead to the beneficial results of the present claims." The Examiner responds that it is applicants burden to

show the beneficial results. The Examiner has set forth the unpredictability of making and/or using applicants claimed invention.

Applicants argue that the sequence of ESA is provided, and that specific examples of native and modified proteins have been provided. Applicants also state that high lysine and high sulfur containing proteins are described on pages 6 and 7 of the specification, and that methods for site-directed mutagenesis were known, and these sequences can be easily tested. Applicant argues that the determination of undue experimentation is not focused on the entire genus, but on the amount of experimentation required to practice any particular member. The Examiner maintains that the specification only demonstrates increased lysine obtained by using one construct of HT12 and an endosperm specific promoter. The specification does not demonstrate the successful use of any other constructs to increase lysine, and that the standard for undue experimentation includes the amount of experimentation required to identify the coding sequence and promoter combinations that will be successful to increase lysine. Given the vast number of possible sequence combinations encompassed by the claims, the absence of guidance for identifying those sequence combinations that will be successful, the lack of working examples of other sequences that result in increased lysine, it would require undue experimentation to make and/or use the invention as broadly claimed.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 are rejected under 35 U.S.C. 102(e) as being anticipated by Falco et al (U.S. Patent 5,773,691). This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants question if the rejection is an anticipation or an obviousness rejection. The Examiner maintains that the rejection is an anticipation rejection. The recitation of "obvious" in the statement of the rejection was inadvertent. Applicants assert that Falco does not disclose the combination recited in the present claims. The Examiner maintains that Falco does teach an endosperm specific promoter operably linked to DNA encoding lysine rich proteins that meet all the limitations of the present claims.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 remain rejected under 35 U.S.C. 103(a) as being obvious over Rao et al (U.S. Patent 5,885,802) in view of Applicants' Admission. This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants assert that no motivation has been provided to use an endosperm preferred promoter in combination with the teachings of Rao. The Examiner maintains that it would have been obvious to substitute an endosperm preferred promoter in the method of Rao given that Rao's invention is drawn to producing elevated levels of methionine in seeds.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 remain rejected under 35 U.S.C. 103(a) as being obvious over Rao et al (U.S. Patent 5,990,389) in view of Applicants' Admission. This rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001.

Applicants' arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicants assert that no motivation has been provided to use an endosperm preferred promoter in combination with the teachings of Rao. The Examiner maintains that it would have been obvious to substitute an endosperm preferred promoter in the method of Rao given that Rao's invention is drawn to producing elevated levels of methionine in seeds.

Applicants assert that no unexpected results are necessary in the absence of a prima facie case of obviousness. However, applicants argue that unexpected results have been provided in Table 1 of the specification and in the Declaration of Jung. The Examiner maintains that the rejection is proper. In Table 1, no statistical analysis is provided, the data is based on only one representative sample from one transformation event. In addition, the data in Table 1 shows that the gbl1 (embryo-preferred) promoter construct resulted in higher levels of the sulfur containing amino acid, cysteine, than the gamma zein and waxy (endosperm-preferred) promoter construct. It is noted that arginine is not a sulfur containing amino acid. Therefore, the data in Table 1 does not support applicants assertions. Additionally, in view of the broad scope of the claims which encompass any endosperm-preferred promoter and any plant seed protein transformed into any cereal plant, it is submitted that the invention is still obvious in view of the prior art references. The scope of the claimed invention should be limited to the teachings of unexpected results.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

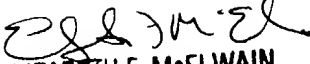
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
March 6, 2003

Application/Control Number: 09/020,716
Art Unit: 1638

Page 9


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600